C. REMARKS/ARGUMENTS

1. Status of th Claims

Claims 1-29 are currently pending in the application. Claims 1, 14, and 17 are independent. Claims 2-13 depend on claim 1. Claims 15-16 depend on claim 14. Claims 18-29 depend on claim 17.

Claims 1, 14, 17, and 22 have been amended. Claim 22 has been amended solely in order to correct a technical error, namely an erroneous recital of the claim upon which claim 22 depends.

No new matter is added by the amendments to claims 1, 14, 17, and 22. Support for these amendments can be found throughout the specification, as discussed in full below.

2. Amendment to the Specification

The amendment to the specification is made in order to correct a typographical error (a mistake in a reference numeral referring to an element in Figure 5b), and does not add any new matter.

3. Rejection of Claims 1-29 Under 35 U.S.C. § 101

Claims 1-29 stand rejected under 35 U.S.C. 101. The Examiner stated that the claimed invention is directed to non-statutory subject matter, and that the claims inferentially claim the human body. The Examiner suggested "replacing 'A fiducial apparatus to be inserted into a target region' to --A fiducial apparatus **adapted to** be inserted into a target region--."

Regarding claim 1, Applicant submits that there is no language in claims 1, or in the specification which limits the "target region," to the human body. Moreover, claim 11, which depends on claim 1 states "*wherein the target region comprises a target region within a human body,*" clearly indicates that the 'target region' in claim 1 includes regions other than regions within a human body, by claim differentiation. For these reasons, Applicant submits that neither claim 1, nor claims 2-13 dependent on claim 1,

inferentially claim a human body.

Nevertheless, Applicant has amended independent claim 1, in accordance with the Examiner's suggestions, i.e. replaced "A fiducial apparatus to be inserted into a target region" to – A fiducial apparatus adapted to be inserted into a target region.

Applicant submits that amended independent claim 1, as well as claims 2-13 dependent thereon, are not directed to non-statutory subject matter, and therefore not invalid under 35 USC 101.

Independent claim 14 is directed toward "A method for anchoring a fiducial in a target region." Applicant submits that independent claim 14, as well as claims 15-16 depending on claim 14, does not inferentially claim the human body, since there is no language in claim 14, or in the specification, which limits the "target region" to the human body. See e.g. specification page 4, lines 10-13, which states that the apparatus and method of Applicant's invention can be used "to locate a portion of any object that is not readily viewable for a variety of different purposes." (underlining added.). Accordingly, Applicant submits that independent claim 14, as well as claims 15-16 depending on claim 14, are not directed to non-statutory subject matter, and therefore not invalid under 35 USC 101.

Independent claim 17 is directed toward "*A fiducial apparatus.*" Claim 17 further recites that the fiducial apparatus includes "*means for anchoring the body portion into a target region . . . .* " Applicant submits that independent claim 17, as well as claims 18-29 depending on claim 17, does not inferentially claim the human body. This is seen by specification page 4, lines 10-13, referenced above, as well as by claim 27, which recites that the target region comprises a target region within a human body. Accordingly, Applicant submits that independent claim 14, as well as claims 15-16 depending on claim 14, are not directed to non-statutory subject matter, and therefore not invalid under 35 USC 101.

In sum, Applicant submits that claims 1-29, as currently submitted, do not inferentially claim the human body, are not directed to non-statutory subject matter, and thus are not invalid under 35 USC 101.

4. **Rejection of Claims 1-3, 10-15, 17-19 and 26-29 Und r 35 U.S.C. § 102(e)**

Claims 1-3, 10-15, 17-19 and 26-29 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,371,904 by Sirimanne ("Sirimanne"). The Applicant respectfully traverses these rejections.

In response to the Examiner's rejections, Applicant has amended independent claims 1, 14, and 17.

In particular, Applicant has amended independent claim 1 to recite that the fiducial apparatus be adapted to be inserted into a target region that includes tissue. Applicant has further amended claim 1 to recite that the anchoring devices be configured to anchor the fiducial apparatus within the target region.

Applicant has amended independent claim 14 to recite a method for anchoring a fiducial in a target region that includes tissue.

Applicant has amended independent claim 17 to recite that the fiducial apparatus include means for anchoring the body portion into a target region that includes tissue. These amendments add no new matter, and are fully supported by the specification. See e.g. Applicant's specification p. 2, lines 13-15 ("*The anchored fiducial apparatus in accordance with the invention anchors itself when it is placed into the region (of tissue) so that the anchored fiducial does not move/change its location relative to the region over time.*)

The invention recited by amended independent claims 1, 14, and 17 is different from the device disclosed and described in Sirimanne. In contrast to the fiducial apparatus of Applicant's invention, which is configured to be inserted into a non-void target region (e.g. a target region within a patient's body, the target region being formed of tissue), the device disclosed in Sirimanne is a cavity marking device adapted to be inserted into an empty body cavity, e.g. a lumpectomy site. The cavity marking device is used to determine the location and orientation of a body cavity, not to track and locate a non-void target region.

Further, the cavity marking device in Sirimanne does not include anchoring devices that are connected to a body portion. Rather, the cavity marking device of Sirimanne self-expands within the empty cavity, upon insertion, so as to anchor itself

within the cavity.

As known, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." See *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984).

Applicant submits that Sirimanne does not anticipate amended independent claims 1, 14, and 17. Applicant does not find in Sirimanne any disclosure of any fiducial apparatus adapted to be inserted into a non-void target region, where the target region is not an empty cavity but rather consists of tissue (e.g. tumorous tissue). Nor does Applicant find in Sirimanne any disclosure of any anchoring devices in addition to body portion, and that is configured to anchor the fiducial apparatus into such a target region. In contrast, in Sirimanne the cavity marking device consists of a body that is made of resilient material, so that upon insertion into a cavity, the resilient cavity marking device can self-expand, substantially filling the cavity. See Sirimanne col. 5, lines 3-11. Applicant does not find any disclosure in Sirimanne of any anchoring devices that are connected to the body portion of the marking device, and that are configured to anchor the marking device into a non-void target region. Applicants' above statements distinguishing the claimed subject matter over the cited document are not to be interpreted as admissions that the cited document is prior art.

Specifically, Applicant submits that Sirimanne fails to disclose, teach or suggest at least the following limitations of independent claims 1, 14, and 17:

Claim 1 (underlining added):

a) *a fiducial apparatus adapted to be inserted into a target region, the target region including tissue;*

b) *one or more anchoring devices connected to the body portion and configured to anchor the fiducial apparatus within the target region;*

c) *each anchoring device having an unanchored position and an anchored position, the unanchored position permitting the body portion to move within the target region and the anchored position anchoring the fiducial apparatus into the target region.*

Claim 14 (underlining added)

a) *A method for anchoring a fiducial in a target region that includes tissue;*

b) *inserting the fiducial into the target region, the fiducial having an anchoring device that anchors the fiducial into the target region;*

Claim 17 (underlining added)

a) *means for anchoring the body portion into a target region so that the fiducial apparatus cannot move, the target region including tissue,*

b) *the means for anchoring the body portion having an unanchored position and an anchored position, the unanchored position permitting the body portion to move within the target region and the anchored position anchoring the fiducial apparatus into the target region.*

For these reasons, Applicant submits that there is no proper basis for the § 102(b) rejection of independent claims 1, 14, and 17, which are not anticipated by Sirimanne. Applicant respectfully submits that claims 1, 14, and 17, as currently amended, are allowable, and that claims 2-3, 10-13, 15, and 18-19 are allowable at least as depending from an allowable base claim.

In addition, following is a claim-by-claim response to the reasons that have been stated by the Examiner for rejecting claims 1-3, 10-15, 17-19 and 26-29.

Regarding claims 1, 2, 13-14, 17-18, and 29, the Examiner states that: "Sirimanne et al. teaches a fiducial apparatus to be inserted into a target region, comprising a body portion made of a material that is visible using electromagnetic radiation, including radioopaque or echogenic (col. 2, lines 54-60); and one or more anchoring devices connected to the body portion (col. 5, lines 4-11), each anchoring device having an unanchored position and an anchored position (col. 13, lines 54-62), the unanchored position permitting the body portion to move within the target region and the anchored position anchoring the fiducial apparatus into the target region (col. 13, lines 63-67 and col. 14, lines 1-6)."

Applicant disagrees, and submits that col. 5, lines 4-11 does not mention any anchoring devices connected to any body portion. In contrast, col. 4, lines 4-11 describe a cavity marking device that self-expands upon insertion into a cavity, without

using any anchoring devices for anchoring itself to the cavity. See col. 4, lines 6-11 of Sirimanne: ". . . *unlike the marking clip which has the potential of attaching to loose tissue and moving after initial placement, the marking device self-expands upon insertion into the cavity, thus providing resistance against the walls of the cavity thereby anchoring itself within the cavity.*"

Applicant further submits that col. 13, lines 63-67 and col. 14, lines 1-6 do not describe any anchoring device for a fiducial apparatus, nor describe any anchoring device having an unanchored position that permits a body portion of the fiducial apparatus to move within a non-void target region. These portions of Sirimanne describe markers made of shape memory metal, which e.g. may assume a collapsed profile (suitable for deployment) when placed in a deployment tube, and may assume a spherical shape to fill a cavity, when exiting the deployment tube and entering into the cavity. However, these portions of Sirimanne do not describe any unanchored position that permits any body portion of any fiducial apparatus to move within any non-void target region. The collapsed profile of the marker in Sirimanne permits the marker to move along a deployment tube, but does not permit any body portion of any fiducial apparatus to move within a target region composed of tissue. Also, these portions of Sirimanne do not describe any anchoring devices for the markers.

Regarding claims 3 and 19, the Examiner states that "Sirimanne et al. '904 teach the body portion comprising a memory metal member that bends in response to an appropriate signal to anchor itself into the target region (see col. 13, lines 57-62)."

Applicant disagrees, and submits that Col. 13, lines 57-62 of Sirimanne does not mention any bending in response to any signal. Rather, col. 13 lines 57-62 mentions a marker which, when deployed into a biopsy cavity, assumes a predetermined configuration to substantially fill the cavity. No bending or responding to any signal is mentioned.

Regarding claims 11-12 and 27-28, the Examiner states: " Sirimanne et al. '904 teach the target region comprising a target region within a human body such as a tumor (see col. 1, lines 20-58)." Applicant disagrees, and submits that, in contrast to the Examiner's statements, col. 1, lines 20-58 (which relate to the background art, and not

to the invention itself of Sirimanne) do not mention a target region such as a tumor for a fiducial apparatus. Rather, col. 1, lines 20-58 discuss biopsy cavities, i.e. the empty site that results after the removal of a tumor or lesion; col. 1, lines 20-58 further discuss the desirability of determining the location, orientations etc. of the subcutaneous cavity from which the lesion has been removed, and of examining the biopsy sites after removal: ". . . *There is an important need to determine the location, most notably the center, as well as the orientation and periphery (margins) of the subcutaneous cavity from which the lesion is removed. . . . a follow-up examination of the biopsy site is often performed to ensure the absence of any suspect tissue and the proper healing of the cavity from which the tissue was removed. . . .* "

Regarding claim 15 and 17, the Examiner states: " Sirimanne et al.'904 teach the insertion further comprising injecting the fiducial into the target region using a needle (see device 400 in Figures 4A-4C)."

Applicant disagrees, and submits that device 400 in Figures 4A-4C show the injecting (with a needle) of a cavity marker device into an empty cavity, not into a target region made of tissue, as recited in Applicant's claims.

Regarding claims 10 and 26, the Examiner states: "Sirimanne et al'904 teach wherein the anchor member is an elongated rectangular shaped member that embeds into the target region (see Figure 1C)."

Applicant disagrees, and submits that Figure 1C does not teach any anchor member that is an elongated rectangular shaped member, and in fact does not teach any anchor member at all. Rather, Figure 1C illustrates a body, not an anchor member, of a cavity marking device that is adapted to be inserted into an empty cavity. See Sirimanne Col. 7, lines 13-16 (". . . *the body may also have an irregular or random shape . . .* ***Body (106) of FIG. 1C*** *is an example of such an irregular body shape. The particular body shape will be chosen to best match to the biopsy cavity in which the device is placed . . .* ")

5. **Rejection of Claims 4-6 and 20-22 Under 35 U.S.C. § 103(a)**

Claims 4-6 and 20-22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne in view of U.S. Pat. No. 5,562,641 to Flomenblit ("Flomenblit"). Applicant respectfully traverses.

Flomenblit is directed to a medical stent to be placed within a tubular organ so as to maintain the diameter of the organ to a desired size. The medical stent is made of two-way shape memory alloy. The two-way shape alloy is conditioned so that 1) in a super-elastic state, the alloy takes on a shape with a wider diameter, and in a 2) soft state, the alloy takes on a narrower diameter. Flomenblit does not teach or suggest any anchoring devices for anchoring a fiducial apparatus within a non-void target region, so that the location of the target region can be tracked.

As discussed above, Sirimanne is directed to a cavity marking device to be inserted into body cavities.

Applicant respectfully submits that neither Sirimanne nor Flomenblit, either alone or in combination, teaches or suggests the subject matter of independent claims 1 (upon which claims 4-6 depend) and 17 (upon which claims 20-22 depend), namely 1) a fiducial apparatus to be inserted into a non-void target region; that 2) includes anchoring devices, each anchoring device having an unanchored position permitting the body portion of the fiducial apparatus to move within the non-void target region; 3) each anchoring device further having an anchored position anchoring the fiducial apparatus into the non-void target region. All of these limitations are included in claims 4-6 and 20-22, which depend on claims 1 and 17, respectively.

It is well established that, in rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). "The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done." In Re San Su Lee, 277 F.3d 1338 (CAFC 2002).

Applicant submits that the Examiner's rejection of claims under 35 U.S.C. 103 does not establish a *prima facie* case of obviousness, because: 1) neither Sirimanne nor Flomenblit either alone or in combination, teaches or suggests the subject matter of

claims 4-6 and 20-22; and 2) neither Sirimanne nor Flomenblit suggest in the desirability of modifying the apparatuses of Sirimanne or Flomenblit, to obtain the subject matter recited in claims 20-22.

In is known that the evidence of record must identify an objective source for the motivation to combine Sirimanne with Flomenblit in the manner proposed. "The mere fact that the prior art *may* be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Fritch, 972 F.2d 1260, 1266, 12 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). Applicant submits that nowhere in Sirimanne or Flomenblit is there any suggestion of the desirablity to combine Sirimanne or Flomenblit, as proposed by the Examiner, to obtain an anchored fiducial apparatus as recited in claims 4-6 and 20-22.

For these reasons, Applicant submits that there is no proper basis for the 35 U.S.C. 103 rejection of claims 4-6 and 20-22, which are not rendered obvious by Sirimanne further in view of Flomenblit.

In addition, following is an item-by-item response to the reasons that have been stated by the Examiner for rejecting claims 4-6 and 20-22.

Regarding claims 4-5 and 20-21, the Examiner states: "Sirimanne et al'904 do not explicitly teach that an appropriate signal further comprises an electric field or a predetermined temperature. In the same field of endeavor, Flomenblit et al '641 teach the use of an appropriate signal further comprising a predetermined temperature to insert a coiled structure into the area of interest (see col. 2, lines 61-67 and col. 3, lines 1-64). Note that an electric field is required to change the temperature since an electronic apparatus is used. It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al. '904 and incorporated the teachings of Flomenblit et al. '641 in order to introduce the coiled marker (such as the one indicated in Figure 5D of Sirimanne et al'904) into the area of interest."

Applicant disagrees. Applicant submits that col. 2, lines 61-67 and col. 3, lines 1-64 of Flomenblit teach a two-way shape memory alloy, with two transition temperatures: a first temperature in which it changes from a soft state into a super-elastic state; and a

second temperature, in which it changes from the superelastic state into the soft state. Col. 2, lines 61-17 and col. 3 lines 1-64 further teaches that after insertion into a tubular organ, the stent is heated so that the diameter of the stent increases to its super-elastic state, and the stent presses on the walls of the tubular organ. Applicant submits that even if these teachings of Flomenblit are combined with Sirimanne, as proposed by the Examiner, the proposed combination would not teach all the elements of claims 4-5 and 20-21, namely a fiducial apparatus that includes a body portion and one or more anchoring devices, wherein the anchoring device has an unanchored position that permits the body portion to move within the target region into which the fiducial apparatus is inserted. Nothing in Flomenblit teaches any body portion that moves within the target region when an anchoring device connected to the body portion is in an unanchored position.

Regarding claims 6 and 22, the Examiner states: "Sirimanne et al. '904 teach the memory metal further comprising nitinol (see col. 13, lines 54-62)." Applicant submits that claims 6 and 22 are not rendered obvious by Sirimanne and Flomenblit, regardless of any disclosure in Sirimanne about nitinol, because claims 6 and 22 respectively depend on claims 4 and 19, and therefore also include all the limitations of claims 4 and 19, which are neither taught nor suggested by Sirimanne and Flomenblit (either alone or in combination), as discussed above.

6. <u>Rejection of Claims 7-9, 16 and 23-25 Under 35 U.S.C. § 103(a)</u>

Claims 7-9, 16, and 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne in view of U.S. Pat. Application Serial No. US 2004/0024304A1 to Foerster ("Foerster"). Applicant respectfully traverses.

Foerster is directed to devices for marking tissue, for example to identify the location of biopsy. The marking device in Forster includes one or more marker elements. The marker element can be formed into a predetermined shape (e.g. helix). The marker elements may include a spring, which may be formed as a coil from which a pair of attachment members extend.

Foerster does not teach or suggest any fiducial apparatus that is composed of a

body portion plus one or more anchoring devices connected to the portion, where each anchoring device has an unanchored position and an anchored position, and where the unanchored position of the anchoring device allows the body portion to move within the target region.

As discussed above in section , Sirimanne is directed to a cavity marking device for insertion into an empty cavity.

Applicant submits that neither Sirimanne nor Foerster suggests any desirability of, or motivation for, modifying Sirimanne to incorporate the teachings of Foerster, in the manner proposed by the Examiner. Accordingly, the record does not appear to establish the requisite motivation for combining Sirimanne and Foerster.

Furthermore, Applicant submits that the proposed combination of Sirimanne and Foerster fails in any case to teach or suggest all the limitations of claims 7-9, 16, and 23-25, as explained below.

Foerster does not teach or suggest at least the following limitations of claims 1, 14, and 17:

- *"a fiducial apparatus . . . comprising a body portion . . . and one or more anchoring devices connected to the body portion, each anchoring device having an unanchored position . . . permitting the body portion to move within the target region."* (Claim 1)
- *"a method for anchoring a fiducial in a target region, . . . the fiducial having an anchoring device that anchors the fiducial into the target region, the anchoring device being held closed while being inserted into the target region . . . the anchoring device opening as the fiducial has been inserted into the target region."*

and

- *"a fiducial apparatus comprising . . .a body portion and . . . means for anchoring the body portion into the target region . . . each anchoring device having an unanchored position . . . permitting the body portion to move within the target region."* (Claim 17)

Further, Sirimanne fails to teach or suggest a number of limitations (as listed in section) in claims 1, 14, and 17.

Accordingly, Applicant submits that neither Sirimanne nor Foerster, either alone or in combination, teaches or suggests all the limitations of claims 7-9, 16, and 23-25, which include all the limitations of claim 1, 14, and 17. Specifically, because claims 7-9 depend on claim 1, claims 7-9 include all the limitations of claim 1; because claim 16 depends on claim 14, claim 16 includes all the limitations of claim 14; because claims 23-25 depend on claim 17, claims 23-25 include all the limitations of claim 17.

For these reasons, Applicant submits that there is no proper basis for the 35 U.S.C. 103 rejection of claims 7-9, 16, and 23-25, which are not rendered obvious by Sirimanne and Foerster.

In addition, following is an item-by-item response to the reasons that have been stated by the Examiner for rejecting claims 7-9, 16, and 23-25. .

Regarding claims 7 and 23, the Examiner states: "Sirimanne et al.'904 do not explicitly teach an anchoring device further comprising an anchor member and an elastic member connected to the anchor member that urges the anchor member into the anchored position. In the same field of endeavor, Foerster et al '304 teach a spring structure (or an elastic member) connected to the anchor member that urges the anchor member into the anchored position (see paragraph 0019). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al.'904 and incorporated the teachings of Foester et al. '304 of incorporating a spring structure that enhances the implantation of the marker (as explained by Foester et al. '304 in paragraph 0019)."

Applicant disagrees, and submits that Foerster, which directed to a device for marking tissue, is not in the same field of endeavor as Sirimanne, which is directed to a device for marking empty cavities. Applicant further submits that modifying Sirimanne to incorporate the spring structure of Foester would not result in the subject matter claimed in claims 7 and 23, since the resulting device would not be a fiducial apparatus (adapted to be inserted into a target region formed of tissue) that includes any anchoring device that has an unanchored position in which the body portion is permitted to move within the target region.

Regarding claims 8-9 and 24-25, the Examiner states: "Foester et al. '304 teach an anchor member comprising a spike that embeds itself into the target region or a pyramidal shaped member (see Figures 17, showing multiple spikes or multiple pyramidal members)."

Applicant submits that modifying Sirimanne to incorporate the spikes or the pyramidal structures of Foester would not result in the subject matter claimed in claims 7 and 23, since the resulting device would not be a fiducial apparatus (adapted to be inserted into a target region formed of tissue) that includes any anchoring device that has an unanchored position in which the body portion is permitted to move within the target region.

Regarding claim 16, the Examiner states: "it would have been obvious to one skilled in the art at the time that the invention was made to have moved one or more anchor devices into an anchored position in order to embed the one or more anchor devices into the target region, depending on the size of the target of interest, requiring more marking identification, as this is a well known practice to those skilled in the art."

Applicant disagrees, and submits that the cited references must be viewed without the benefit of impermissible hindsight. Applicant further submits that, regardless of whether moving one or more anchoring devices into an anchored position would have been obvious to one skilled in the art at the time that the invention was made, claim 16 is not rendered obvious by Sirimanne or Foerster, because neither Sirimanne nor Foerster, either alone or in combination, teaches or suggests all the elements of claim 14, upon which claim 16, as explained above.

7. Conclusion

On the basis of the foregoing amendments, Applicant respectfully submits that all of the pending claims are in condition for allowance. An early and favorable action is therefore earnestly solicited. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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